

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

November 2, 1999

## **MEMORANDUM**

**SUBJECT: Dicrotophos** (List A, Reregistration Case No. 0145). HED Responses to Amvacs

Comments to HED's Risk Assessment for Reregistration Eligibility Document (RED.) Chemical No: 035201; DP Barcode: D260060; MRID: None.

**FROM:** David E. Hrdy, Biologist

Chemistry and Exposure Branch 2 Health Effects Division (7509C)

**THROUGH:** Susan V. Hummel, Branch Senior Scientist

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**TO:** Michael Nieves/Stephanie Willett, Chemical Review Managers

Registration Branch

Special Review and Reregistration Division

Health Effects Division's (HED's) revision of the risk assessment document for dicrotophos was completed in a separate memorandum.

This HED Memorandum addresses AMVAC's letter, dated October 4, 1999, entitled "Comments on the dicrotophos risk assessment (errors only.)" This memo replies only to comments numbered 1 through 16, which were in regard to HED's risk assessment. These comments are numbered as items below. This cover memo details the registrants comments and HED's response to these comments and the resulting changes incorporated into the document. Responses concerning supporting documents (e.g. dicrotophos ORE chapter or the dicrotophos Product and Residue Chemistry chapter) were given comments in AMVAC's letter. Unless deemed to be specifically relevant to the risk assessment chapter, AMVAC's comments relating to other chapters were not addressed herein. However, these remaining comments are being considered and will be incorporated as appropriate in the final HED dicrotophos risk assessment.

Item #1 On page 4, paragraph number 5, line 4, '0.01 ppm' should read '0.01 ppb.'

**HEDs Response:** We concur with this finding and the change has been made in the risk

assessment.

Item #2 The vapor pressure should read 2.2 x 10-5 mm Hg at 20° C and/or 2.9 mPa at 20°

C. See MRID 44834801.

**HEDs Response:** HED concurs with this vapor pressure value (reviewed by D. Hrdy,

D256588,dated 11/1/99.) HED has updated the risk assessment to reflect

this change.

Item #3 Pg. 8; Additional comments have been provided on the rabbit teratology study and

as far as Amvac knows it is still acceptable.

**HEDs Response:** This study was classified as unacceptable in a memo. The following is the

executive summary from this memo (HED Doc #013049, dated 16

December 1998.)

"The developmental toxicity study in rabbits is classified Unacceptable-Guideline and does not satisfy the guideline requirement for a series §83-3b developmental toxicity study in rabbits. The study is not upgradable due to study deficiencies, i.e. inadequate identification of the test material (stability), absence of individual daily observations and food consumption, individual uterine examination including number of fetal deaths, early and late resorptions and number of viable fetuses/sex, individual litter weights and fetal weights/sex/litter, and individual fetal external examination. The lack of detail was quite apparent in the study report." Dated, 12/16/98; DP Barcode: D251710, HED DOC Number: 013049.

**Item #4** Pg. 8; A DCI has been issued for a developmental neurotoxicity study.

**HEDs Response:** No comment necessary.

**Item #5** Pg. 8; Identification of the Acute Delayed Neurotoxicity - Hen as a data gap does

not correspond to the comment on page 7 paragraph 3, line 13, where it states that

there was no evidence of delayed neurotoxicity in the hen study.

**HEDs Response:** Hen neurotoxicity study does not appear to be a data gap according to

HED Document #002181.

**Item #6** Pg. 12; 'Monocroptophos' should read 'monocrotophos.'

**HEDs Response:** This spelling error has been corrected.

Item #7 Pg 15; Delete 'week' and 'Hanfor' should be 'Hanford.'

**HEDs Response:** These errors were corrected.

**Item #8** See comment 2.

**HEDs Response:** See response to Item #2.

**It is highly unlikely that a 3 x 0.5 lb i.a./acre would be used.** The maximum is

more likely to be 0.2/0.5/0.5 lb ai/acre.

**HEDs Response:** We reserve comment in anticipation of EFED's response with regard to

water modeling issues.

**Item #10** See comments on Item 3.

**HEDs Response:** See response to Item #3.

**Item #11** 'liquid (aqueous)' should read 'liquid (isopropyl alcohol based).'

**HEDs Response:** HED concurs and has made the appropriate correction.

Item #12 An acute delayed neurotoxicity study has been done and will be submitted to the

Agency.

**HEDs Response:** HED notes this comment.

**Item #13** See comments on Item 3.

**HEDs Response:** See HEDs response to Item #3.

Item #14 An acute inhalation is available and Amvac has submitted additional comments. No DER has been issued so Amvac is not clear why this has been identified as a data gap.

**HEDs Response:** Acute inhalation is not considered a data gap, the risk assessment has been corrected to reflect this.

Item #15 A 21 day dermal study in the rabbit is available and Amvac has submitted additional comments. No DER has been issued so Amvac is not clear why this has been identified as a data gap.

**HEDs response** The 21 day dermal study <u>is</u> a data gap at this time (*HED Doc #008034*, *dated 16 July 1999*.)

**Item #16** Both a 90 neurotoxicity study and a chronic study in the rat have been submitted so Amvac is not clear why this study has been identified as a data gap.

**HEDs response**Both studies are not a data gap, recently submitted studies were deemed acceptable. The 90 day feeding study in rats, however, <u>is</u> a data gap (*HED Doc # 002181, MRID # 00066334.*)

cc: Chem F, Chron F. GOtakie RDI:Team: 11/2/99; SVH:11/2/99

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